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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,072	08/06/2003	James Lousararian	ANG 00.03 CIP5	9838
32047	7590	09/19/2007		
GROSSMAN, TUCKER, PERREAULT & PFLEGER, PLLC 55 SOUTH COMMERICAL STREET MANCHESTER, NH 03101			EXAMINER YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17 and 48-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 August 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson, IV et al. (hereinafter "**Williamson**"), U.S. Patent No. **5,972,004**

Claims 1 and 50: Williamson discloses an individual staple ("fastener") **10U** having a proximal end **14** adapted for individual attachment to a single-staple delivery device **40**, the staple having a plurality of distally extending prongs **16**, **18** commonly connected to the proximal end and having tissue-piercing distal tips, a pledget **P** being pre-attached to the staple and being embraced by the prongs, the pledget having surfaces configured

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to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple, which are preformed before attachment to the staple, and to enable the combined staple and attached pledget to be advanced together, by a single-staple delivery device, toward an arteriotomy, whereby when the prongs of the staple are engaged with tissue about the arteriotomy and are closed about the arteriotomy, the pledget will be disposed and retained adjacent the arteriotomy (Figures 2-5, 25-26; col. 7, lines 60-67, col. 12, lines 15-59).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4, and 48 rejected under 35 U.S.C. 103(a) as being unpatentable over **Williamson** (U.S. Patent No. **5,972,004**) in view of **Kugel** (U.S. Patent No. **5,634,931**).

Claims 3, 4, and 48: Williamson discloses the claimed device except for the pledget comprising a plurality of peripherally extending tabs configured to be received between said plurality of prongs, a plurality of holes, each adapted for receiving one of said plurality of prongs, and a plurality of peripheral notches, each of the prongs being disposed within one of the notches.

Kugel teaches a pledget comprising a plurality of peripherally extending tabs **62** configured to be received between said plurality of prongs, a plurality of holes **59**, each

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adapted for receiving one of said plurality of prongs, and a plurality of peripheral notches **58**, each of the prongs being disposed within one of the notches in order to frictionally keep the pledget in place (Figures 3 and 5, col. 5, lines 25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of tabs, holes, and notches to the pledget of Williamson, as taught by Kugel, in order to facilitate secure placement of the pledget with the staple and the tissue.

6. Claims 5-17 rejected under 35 U.S.C. 103(a) as being unpatentable over **Williamson** (U.S. Patent No. **5,972,004**) in view of **Dalessandro** (U.S. Patent No. **6,273,897**).

Claims 5-17: Williamson discloses the claimed device except for the pledget comprising a woven or non-woven fabric material comprising polyester material, or being a bioabsorbable polymer sheet, having a physiologically active agent adapted to be released over a predetermined time interval or comprising a coating or being impregnated in the pledget, or being an anti-microbial/antiseptic agent, or being an agent that inhibits intraluminal clotting or promotes extraluminal clotting.

Dalessandro teaches a bioabsorbable pledget (or "buttress") **52** made of a polymer of woven or non-woven fabric material such as polyester and containing physiologically active agents that are released over a predetermined time interval, anti-microbial or anti-septic agents, agents that inhibit intraluminal clotting or promote extraluminal clotting, or agents that comprise a coating or are impregnated in said pledget (Figures 4-6, col. 5, lines 24 to col. 7, line 55). It would have been obvious to

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one of ordinary skill in the art at the time of invention to provide a pledget comprising the above materials and agents, as taught by Dalessandro, to Williamson since they are well known in the art for their biocompatibility and other benefits.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Williamson** (U.S. Patent No. **5,972,004**) in view of **Ginn** (U.S. Patent No. **6,277,140**).

Claim 49: Williamson discloses the claimed device including the prongs being commonly connected at a crown formed at the proximal end of the staple, except for the crown including distally extending tabs or webs adapted to bear against the pledget.

Ginn teaches a staple **62** having four prongs **76** and being commonly connected at a crown **70** including distally extending tabs or webs (near **74**) adapted to bear against the pledget (Figure 28). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the distally extending tabs or webs, as taught by Ginn, to Williamson in order to create a secure engagement between the pledget and the staple.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-17, 48, and 49 have been considered but are moot in view of the new ground(s) of rejection.
2. In regards to the applicant's argument that Kugel does not disclose any kind of pledget or any fastener of any kind, including sutures, staples or the like, in use with the device, and that the tabs do not serve any function relating to staples. The examiner disagrees. Not only is the mesh device a small, absorbent pad, or a pledget by definition, as well as capable of use with a staple, but also Kugel teaches that the mesh may be secured by anchoring stitches (col. 4, lines 62-63) in order to keep the mesh from sliding. The peripherally extending tabs 62 are *configured* to be received between a plurality of staple prongs, and therefore read on the claim limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER